Guidance for Industry

(Pilot Project)

SUBMITTING A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION IN ELECTRONIC FORMAT TO CVM VIA E-MAIL

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
May 1997

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Attachments

GUIDANCE FOR INDUSTRY[1]

SUBMITTING A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION IN ELECTRONIC FORMAT TO CVM VIA E-MAIL

I. BACKGROUND

The Center for Veterinary Medicine (CVM) is developing methods to facilitate submission review by utilizing computers and electronic communications. Since the publication of FDA's Final Rule on Electronic Records and Signatures (21 CFR Part 11) on March 20, 1997, CVM has been preparing to take advantage of the opportunities afforded by this new regulation; i.e., an electronic copy will be accepted by the Agency as the original, in lieu of paper.

The need to transfer information electronically between CVM and sponsors is being accelerated by four factors within CVM:

- reduction in the number of reviewers to manage all incoming paper submissions
- reduction in paper storage capacity
- need for improved efficiency of the review process
- need for a more timely review process

II. PILOT PROJECT

A. Purpose and Scope

To determine the practicality of electronic submission and review as an alternative to the current paper-based processes, CVM has proposed a pilot project which will allow sponsor companies to submit Notices of Claimed Investigational Exemption (NCIE), often referred to as drug shipment notices, as an e-mail attachment via the Internet. The NCIE was selected because of its simplicity, size, and broad use within CVM and by nearly all sponsors.

[1] This guidance has been prepared by the Office of New Animal Drug Evaluation (ONADE) in the Center for Veterinary Medicine (CVM) at the Food and Drug Administration. Although this guidance does not create or confer any rights for or on any person and does not bind FDA or the industry, it does represent the Center's current thinking on submitting a Notice of Claimed Investigational Exemption in electronic format via e-mail. For additional copies of this guidance, access the document on the WWW by connecting to the CVM Home Page at http://www.cvm.fda.gov.

B. Time Frame

CVM anticipates the pilot will begin September 8, 1997, and be conducted for six months, ending on March 9, 1998, with an interim review after three months, on December 8, 1997.

Formal Letters of Intent to participate must be submitted in paper and electronically (via e-mail) to CVM by June 16, 1997 (see Section IV.). Prior to July 18, 1997, the sponsor will receive a response from CVM via U.S. mail and e-mail. Participants will be notified of a training workshop planned for August 1997.

C. Benefits for Sponsors

Major benefits to sponsor companies who choose to participate include an advanced opportunity to develop the internal processes and procedures for producing and managing electronic submissions, as well as immediate feedback regarding the adequacy of their processes. Developing these processes and procedures will reap these significant benefits to a sponsor:

- motivation to organize and cross-reference documentation more systematically than is currently done in a hardcopy submission;

- internal use of the electronic submission to speed review by project team members, enhance information retrieval in response to agency questions, assist in assembly of dossiers for submission in other markets, and ensure a permanent archival copy that can be readily accessible at lower cost than hardcopy storage;

- production of an overall higher quality presentation of information to the Agency.

D. Minimum Requirements to Participate

For purposes of this pilot, the sponsor will use the NCIE format provided by CVM, which will be submitted to CVM as an Adobe® PDF file (created in Adobe Acrobat® Exchange® compatible with version 2.1)[2]; therefore, the sponsor must be able to populate a word processing document with data and convert it to a PDF file.

A sponsor who participates must project at least one drug shipment within the six-month pilot and must also agree to submit all NCIEs in an electronic format for the duration of the pilot. Submissions may be to any of the following CVM divisions: Division of Therapeutic Drugs for Non-Food Animals (HFV-110), Division of Biometrics and Production Drugs (HFV-120), Division of Therapeutic Drugs for Food Animals (HFV-130), and/or Division of Animal Feeds (HFV-220).

[2] FDA use of specific products does not constitute an endorsement of that product.

The sponsor must have MIME-compliant access to the Internet. The sponsor must also agree to use a standardized convention for the subject line of each e-mail transmission (NCIE) and to attach the NCIE as a PDF file to the e-mail message.

E. Security Measures

CVM will assign User IDs to the sponsor contacts listed in a sponsor's Letter of Intent. This unique identification will verify the sender's identity. The User ID will be entered on the NCIE and serve as the electronic signature of the sender.

When the PDF file is created, the sponsor will "lock" the file by creating a password necessary to open the file. The pilot project coordinator from each sponsor will provide CVM with a single "key" (i.e., password) to unlock all submissions from that sponsor for the duration of the pilot.

CVM will acknowledge receipt of the NCIE by creating a new e-mail message (i.e., not by using a "Reply" feature) and sending it to the e-mail address of the sponsor contact with that individual's User ID, using a standardized convention in the subject line (NCIE).

F. Evaluation

The pilot project will be evaluated in the following six areas:

- creation of NCIE by sponsor
- submission of NCIE to CVM by sponsor
- receipt of NCIE by CVM
- review of NCIE by CVM
- electronic filing of NCIE (both CVM and sponsor)
- retrieval of filed NCIE (both CVM and sponsor)

Project benchmarks to be measured at three months and at pilot termination include percentage of successfully sent and received submissions and number of resubmissions necessary. CVM will evaluate the time necessary for scientific review of the submissions and will also measure time between significant milestones of the review process. Metrics will be recorded by both the sponsor and CVM on a Data Capture Form (see Section VII.).

Less quantifiable, but certainly necessary, will be an assessment of the practicality of the project, the feasibility of electronic document storage and archiving, and the perceived comfort level of providing submissions electronically over the Internet. An evaluation of the security measures used will address possible future needs for encryption methods.

The lessons learned during this pilot will assist in determining future directions for electronic submission using other media such as floppy disks, magnetic tape or CD-ROMs and with other document types such as Freedom of Information (FOI) Summaries, study protocols, animal slaughter notifications, product labeling, and data in support of original and supplemental NADAs and ANADAs.

III. ROLES OF ALL PARTIES INVOLVED

A. Background

The success of this project will depend on the diligence and cooperation of all parties involved from both CVM and the regulated industry. Below is a table outlining the roles and responsibilities of all key parties involved in this pilot project..

B. CVM Project Roles, Responsibilities, and Responsible Persons

Role	Responsibilities	Contact
Project Coordinator	Facilitate communication within the Center, and oversee the coordination of the total pilot project.	Dr. Woodrow Knight (301) 594-1600
CVM Electronic Submission Working Group	Provide specifications necessary for the use and processing of electronic submissions. Gather and disseminate information on the current processing of paper submissions, and assist in design of electronic processing procedures. Evaluate the success of the pilot on the efficiency of the review process.	Representatives from each team of Target Animal Review Divisions within the Office of New Animal Drug Evaluation and Division of Animal Feeds and CVM's Information Technology Staff

Role	Responsibilities	Contact
Technical Specialist	Confirm electronic format to be used and the security required in submission of electronic NCIEs are compatible with current CVM LAN configuration. Assess future needs for electronic storage and retrieval of information, and recommend any needed additional capability. Coordinate LAN capabilities for support of the pilot project. Also responsible for compliance with Agency Initiatives and Standards.	Dr. Charles Andres (301) 594-2604
Processing Specialist	Coordinate actual processing, logging, tracking, and storage of electronically submitted and stored submissions. Recommend changes to existing tracking system, and responsible for compatibility of overall system (integration of paper and electronic submissions).	Ms. E. L. Parbuoni (301) 594-1641
Electronic Document Control Unit (e-cvmdcu)	Receive, log, process, and file electronically submitted NCIE.	CVMDCU@bangate.fda.gov (301) 82-STARS (301) 827-8277

C. CVM Pivotal Roles And Summary Of Primary Duties

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- Provide guidance for the total pilot project.
- Coordinate project within the Center and between the industry and the Center.
- Inform Office and Center Management of pilot progress.
- Liaison with Feeds Group (HFV-220).
- Responsible for preparation and clearance of final evaluation report.

Andres	• Develop electronic format in conjunction with industry representatives to be compatible for LAN capabilities of CVM. • Develop security measures to safeguard CVM LAN and confidentiality of received or transmitted information. Address CVM internal security concerns (virus, etc.) • Present training to ONADE Reviewers. • Develop filing system for electronic submissions. • Develop LAN requirements and identify any additional electronic capabilities. • Maintain CVM timeline. • Evaluate CVM's Federal Managers Financial Integrity Act requirements for submission archiving and oversees implementation of such plan. • Liaison with Agency Initiatives and Standards. • Present training to industry participants.
Parbuoni	• Develop processes for receipt, logging, tracking, and filing of electronically formatted submissions. • Prepare flow chart for internal processing of electronic submissions. • Prepare SOPs and train Document Control Unit (DCU) if pilot project is successful and becomes policy. • Prepare reports for monitoring electronic submission process throughout the pilot project. • Compile and prepare "statistics" at completion of project. • Assist in writing SOPs at completion of the project. • Collate data from Data Capture Forms.
Team Representatives	• Assist in developing the electronic form to be used for NCIE. • Provide assistance to reviewers within their respective teams during the pilot. • Recommend processing procedures for electronic submissions. • Design training project for reviewers. • Provide evaluation during and at the end of the project, including suggestions for changes, modifications and future direction of the project.
e-CVMDCU	• Log submissions on a daily basis, route submission to review organization, and complete STARS record. • File archival copy of the NCIE. • Route any necessary copies within the Center. • Complete Data Capture Forms.

D. Sponsor Project Roles, Responsibilities, and Responsible Persons

Role	Responsibilities
Sponsor Pilot Project Coordinator	Coordinate project within the sponsor and between the sponsor and CVM. Confirm electronic format to be used and the security required in submission of electronic NCIEs are compatible with the sponsor's computer configuration. Assess needs for electronic storage and retrieval of information, and recommends any needed capabilities. Coordinate internal process capabilities for support of the pilot project. Also responsible for compliance with 21 CFR 11.
Sponsor Contacts	Process, prepare and file electronically submitted NCIE and ensure appropriate filing of the electronic submission. Receive confirmation of successful transmission from e-CVMDCU. Convey pertinent project information to the sponsor pilot project coordinator.

E. Sponsor Pivotal Roles And Summary Of Primary Duties

Sponsor Pilot Project Coordinator

- Coordinate pilot project between the sponsor and CVM.
- Ensure security measures to safeguard computer system and confidentiality of information transmitted and received. Address internal security concerns (virus, etc.).
- Present training to person(s) who prepare NCIEs.
- Develop filing system for electronic submissions. Address computer system requirements and identify any needed capabilities.
- Ensure adherence to Pilot Project timeline.
- Evaluate requirements for electronic file records and oversee implementation of such plan in compliance with 21 CFR 11.
- Develop processes for receipt, logging, tracking, and filing of electronically formatted submissions.
- Prepare flow chart for internal processing of electronic submissions.
- Prepare SOPs and user documentation.
- Prepare reports for monitoring electronic submission process throughout the pilot project.
- Collate Data Capture Forms, by INAD, and submit tabulated information to CVM Processing Specialist.

Sponsor Contacts

- Create NCIE and transmit PDF copy to e-CVMDCU.
- Complete Pilot Project Data Capture Form (DCF).
- Retain NCIE in accordance with internal procedures.
- Forward DCF to the sponsor project coordinator.
- Process confirmation from e-CVMDCU.

IV. LETTER OF INTENT TO PARTICIPATE IN PILOT

Sponsors wishing to participate in the pilot project must amend their pertinent INADs, generic INADs, and IFAs by sending a single Letter of Intent (on paper) to CVM via US Mail, FedEx, UPS, etc. by June 16, 1997, as well as an electronic copy (via e-mail), in order to be eligible to participate in the pilot project (see Attachment A for suggested format of the letter). In this letter, the sponsor shall identify their sponsor project coordinator and sponsor contact(s) that will be submitting the NCIEs. The letter must include all of the following information, which is covered under OMB No. 0910-0117:

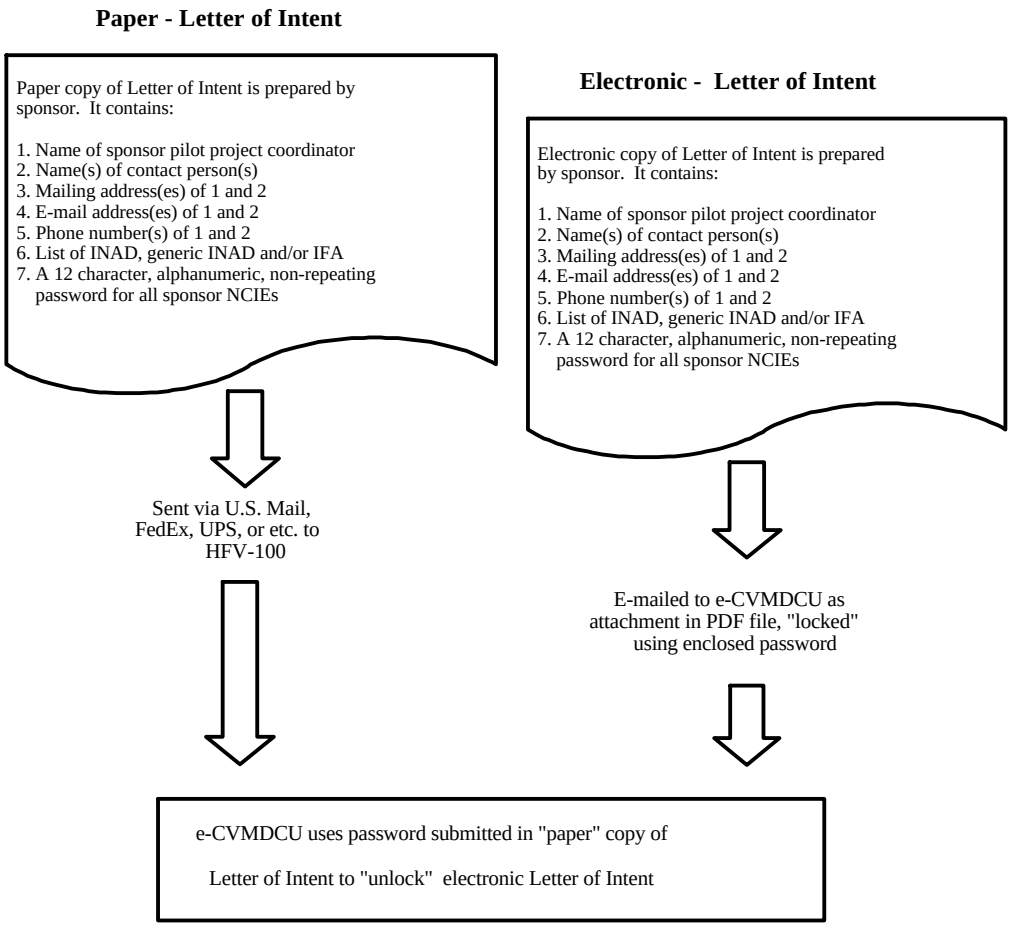
1. name, mailing address, phone number, and e-mail address of sponsor's pilot project coordinator
2. a listing of sponsor's INAD, generic INAD, and/or IFA
3. name(s) of the contact person(s) who will be submitting NCIEs
4. mailing address of each contact person
5. e-mail address of each contact person
6. phone number of each contact person
7. a 12 character, non-repeating, alphanumeric password that will be used to password protect the submitted NCIEs submitted by that sponsor

The paper copy will serve as the "official" submission and a copy will be placed in each of the sponsor's file(s) in CVM's archives. Sponsors need not submit the information to each INAD, generic INAD, or IFA; a list of pertinent files may be provided. The electronic copy (submitted as a "locked" PDF file attachment) will be used to test the sponsor's electronic submission capabilities and compatibility with CVM.

The electronically submitted file will be unlocked using the password transmitted in the paper copy of the Letter of Intent. After CVM successfully accesses the electronic file, a receipt for the Letter of Intent will be generated and sent back to the sponsor's project coordinator as a locked PDF file via e-mail. This electronic receipt will be only a courtesy acknowledgment that the electronic file was received and was accessible. Prior to July 18, 1997, the Center will respond, in paper, to the sponsor with the CVM-generated User ID(s) and other pertinent information necessary for participation in the pilot project.

The flowchart below illustrates the procedures for submission of the paper and electronic copies of the Letter of Intent to CVM.

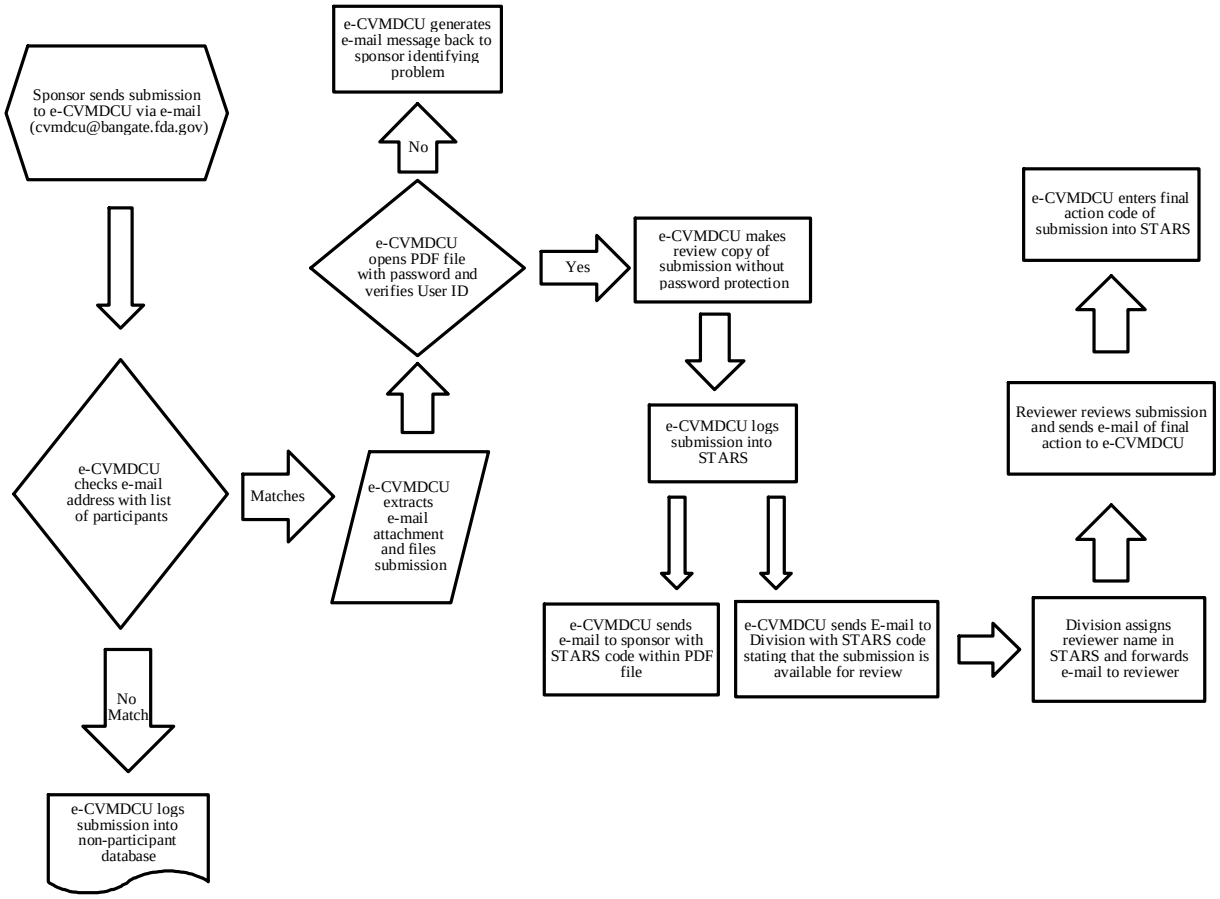
Flowchart 1. Letter of Intent to CVM



V. CVM'S NCIE PROCESSING

The processing of the electronic NCIE (see Attachment B for example of format) begins with the Center receiving the e-mail with the NCIE as an attachment in a PDF file. The flowchart below outlines the anticipated electronic document flow and processes that will be enacted upon receipt of an electronic NCIE within CVM.

Flowchart 2. NCIE Processing



Glossary of terms:

e-CVMDCU Center for Veterinary Medicine Electronic Document Control Unit
PDF Adobe Acrobat Portable Document Format
STARS Submission Tracking and Retrieval System, CVM's document tracking database.

VI. SECURITY MEASURES

The Internet has been used as an expeditious vehicle for the exchange of information by corporations for several years. However, many corporations and government agencies have avoided using the Internet for the exchange of sensitive and/or confidential information because of concerns about security.

In the development of a pilot project using the Internet as our message-carrying vehicle, there are four areas of security that must be addressed adequately by all participants prior to its adoption. These areas are:

- Determine the Disclosure/Non-Disclosure status of the information being shared
- Authentication verification
- Determine the requirements for nonrepudiation
- Develop methods that would eliminate intentional and/or unintentional integrity problems

A. Disclosure/Non-Disclosure

Most information submitted to CVM is confidential in nature. CVM is not at liberty to disclose the existence of/or the information contained in INAD files, NADA applications, etc., to the general public or to other drug sponsors. Therefore, using the Internet to submit NCIE information can be done only with adequate encryption of the information contained within the NCIE. For purposes of this pilot project and the type of information submitted, we are recommending that this encryption be in the form of a password-protected PDF file. At the conclusion of the pilot, we will be assessing the adequacy of this level of security and determine whether or not a more formal "public key - private key" encryption package is necessary.

Protecting the Confidentiality of the Information in the NCIE

When the PDF file is created, the sponsor will lock the file by creating a 12 character, alphanumeric, non-repeating password necessary to open the file. In Adobe Acrobat Exchange, this is done selecting:

File ---------|
Save As ---------|
Security ----------|
Specify Password to Open Document

Each sponsor pilot project coordinator will provide CVM with a single key (i.e., password) to unlock all submissions from all contact persons for that sponsor for the duration of the pilot. CVM will also use the same password when sending acknowledgments of receipt of NCIEs.

B. Authentication Verification

Currently, CVM receives paper submissions from drug sponsors via US Mail, Federal Express, UPS, etc. With these submissions, there is a cover letter on original sponsor letterhead signed by an authorized sponsor official. This information allows CVM to authenticate that the submission is from the stated sponsor. The electronic submission of an NCIE must also provide a means by which CVM can authenticate the origin of the electronic document.

Assignment of User IDs by CVM

The sponsor will amend their investigational files by sending CVM a Letter of Intent to participate in the pilot project. This initial contact will be in paper and electronic (e-mail) form and will contain among other things, a list of names of contact persons who will be transmitting Notices of Claimed Investigational Exemption (NCIE) during the project, their addresses, e-mail addresses, and phone numbers. The letter will also contain the sponsor-supplied password to be used as a key by CVM and the sponsor to open locked PDF file attachments for all future electronic information exchanged during this pilot project. CVM will assign User IDs to each contact person. This unique identification will verify the sender's identity by serving as the electronic signature of the sender on the submitted NCIE forms.

CVM will send each sponsor pilot project coordinator a response to the Letter of Intent, in both paper and electronic form, with a listing of the assigned User IDs. For the electronic form, the listing of User IDs will be in a locked PDF file attached to the e-mail message, which can be opened only by using the password provided by that sponsor to CVM in their Letter of Intent. The purpose of this transmission will be to test the sponsor's ability to receive e-mail from CVM.

Verifying the Sender's Identity

An additional precaution will be taken to ensure that the e-mail message received at CVM did indeed come from the sender designated. CVM will acknowledge receipt of the NCIE by creating a new e-mail message (i.e., not by using a "Reply" feature) and sending it to the e-mail address of the contact person with their User ID assigned by CVM. If that contact person has not sent an e-mail to CVM, but receives an acknowledgment, he/she can suspect that the security of the system has been violated.

C. Requirements for Nonrepudiation

Currently, time-sensitive information is submitted via certified mail so that the sponsor has a record verifying the date and name of individual who received the information at CVM. This also provides a legal basis by which drug sponsors can assert their compliance with laws and regulations.

For NCIEs, drug sponsors are required to submit their drug shipment notices ***prior*** to the shipment of new animal drugs for use in clinical animals [21 CFR 511.1(b)(4)]. Currently, CVM uses the date on the cover letter as the determination whether notification was made prior to delivery. For the purposes of this pilot project, the sponsor will complete a date field within the electronic NCIE. As a means of verifying that the information was received, CVM will respond with an e-mail message back to the sponsor within two business days of its receipt.

Verifying Receipt of the NCIE

The acknowledgment of receipt of the NCIE will be an e-mail message with an attached locked PDF copy of the routing slip taken from CVM's STARS system. The password to open this PDF file is the same as the password provided by the sponsor to CVM. The subject line of the e-mail message will be standardized as "NCIE." No text will be necessary in the body of the e-mail message.

If the sponsor has not received an acknowledgment within three business days of sending in the NCIE, the sponsor contact should call CVM at 301-82-STARS (301-827-8277) to determine the fate of their transmission.

D. Submission Integrity

Currently, the integrity of the accuracy and veracity of the content of a submission to CVM is the responsibility of the drug sponsor. If sections of the submission are missing or illegible, CVM requires the sponsor to provide copies of the missing information or legible copies of the illegible information. Though remote, a possibility exists that intentional or unintentional changes could occur to an electronic submission that would probably not happen to a paper submission. For example, unintentional "scrambling" of the submission may occur during transmission so that CVM receives a corrupted, non-usable file. Further, an example of an intentional change would be if a message were intercepted en route and changes made to the content and then sent on as if from the original sender.

For purposes of this pilot project, we are relying on the password protection of the PDF file to ensure the integrity of the electronic submission. If the file is received by CVM intact and can be unlocked and opened by Adobe Acrobat Reader, then CVM will assume that no changes occurred to the submission once it was e-mailed from the drug sponsor.

VII. PILOT PROJECT EVALUATION

The practicality of electronic submission of NCIEs will be evaluated by CVM at the project mid-point (three months) and at project termination (six months). Benchmarks to be measured include the ability to create and submit a NCIE by sponsor; receipt, processing and review of the NCIE by CVM; and the electronic filing and subsequent retrieval of the NCIE by both CVM and the sponsor. Other aspects of the project will also be assessed, e.g., feasibility of electronic document storage and archiving, and the comfort level of providing submissions electronically over the Internet.

In order to evaluate the benchmarks listed above, it is necessary to record certain information associated with the entire NCIE submission process. Each time the sponsor submits an NCIE (via e-mail) to CVM information will be recorded and maintained. A data capture form has been created to collect the required information (see Sponsor Data Capture Form below). These completed forms will be collected and submitted to CVM by the sponsor pilot project coordinator at the mid-point (three months) and termination (six months) of the pilot project. Similar information will be collected by CVM's electronic Document Control Unit personnel (see CVM Data Capture Form). If the sponsor contacts require assistance in the completion of these forms, they should contact their sponsor pilot project coordinator.

The data recorded in these forms along with other information gathered during the pilot project will be used to determine the success of the project. These data will allow CVM to determine if the procedures used in this pilot project can be extended to other information submitted to CVM to support approval of original and supplemental NADAs and ANADAs.

Sponsor Data Capture Form

SPONSOR NAME:
INAD/IFA:
Study Identification:
Investigational Drug:
Date of NCIE:
Date NCIE Successfully Sent:
NCIE Sent By (Contact):
Number of Resubmission(s):
Date Confirmation Received:
Confirmation Received By:
STARS Submission Code:
Date Filed:
Filed By:
Retrieved From Electronic Files (Yes Or No):
Problems of Any Type:

CVM Data Capture Form

SPONSOR NAME:
INAD/IFA:
Study Identification:
Investigational Drug:
Date of NCIE:
STARS Submission Code:
Date Received:
DCU Recipient:
Date Confirmation Sent:
Confirmation Sent By:
Date Review Completed:
Reviewed By:
Final Action Date:
Final Action Processed By:
Date Filed:
Filed By:
Retrieved From Electronic Files (Yes Or No):
Problems of Any Type:

ATTACHMENT A - Letter of Intent

Robert C. Livingston, Ph.D.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine
7500 Standish Place (HFV-100)
Rockville, Maryland 20855

Dear Dr. Livingston:

This letter is provided to notify the Center for Veterinary Medicine (CVM) of our intent to participate in the pilot project for the electronic submission of Notices of Claimed Investigational Exemption (drug shipment notices) as described in the CVM Guidance for Industry (Pilot Project) document entitled, "*SUBMITTING A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION IN ELECTRONIC FORMAT TO CVM VIA E-MAIL.*"

Beginning September 8, 1997, we will submit all Notices of Claimed Investigational Exemption (NCIE) to CVM electronically in accordance with the above referenced CVM guidance document. An attachment to this Letter of Intent contains the name of the person who will serve as our pilot project coordinator (including mailing address, phone number, and e-mail address) and a listing of our INADs, generic INADs, and/or IFAs, and the names of our contact persons who will be submitting NCIEs, along with their mailing addresses, e-mail addresses, phone numbers, and a 12 character, non-repeating, alphanumeric password that will be used to password protect NCIE files submitted by (Sponsor's Name).

It is our understanding, that CVM will acknowledge our intent to participate in the pilot project with a letter, mailed by July 18, 1997, that contains a User ID for each contact person. We look forward to receipt of that letter.

Sincerely,

ATTACHMENT B - NCIE Format

Notice of Claimed Investigational Exemption

(For purposes of CVM's Pilot Project)

Department of Health & Human Services, PHS
Food and Drug Administration
Center for Veterinary Medicine (HFV-100)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@bangate.fda.gov)

DATE:
INAD/IFA NO:
NAME OF DRUG/ADDITIVE:
STUDY/TRIAL ID:
DRUG SHIPMENT NO:
USER ID:

The sponsor, , submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetic Act. This information is submitted in electronic form.

I. Drug Shipment Information

1. Established name(s) of the drug(s): trade name(s):
2. Proposed use of the drug:
3. Date of drug shipment (or receipt):
4. Total quantity (wt. or vol.) and concentration of drug shipped (or received):
5. Type of study or trial:
6. Pivotal (intended for support of NADA or ANADA): ☐ or nonpivotal: ☐
7. Name and address of investigator:

8. Location of study/trial:

9. Name and address of study monitor:

10. Approximate date of study/trial Start: Finish:
11. Protocol submitted to CVM: ☐ Yes ☐ No
    If Yes, date submitted to CVM and/or CVM submission number:
12. Species of animals:
13. Size and type of animals:
14. Approximate number of animals (in this trial):
    Total: Treated: Control:
15. Number of animals previously used:
    Total: Treated: Control:
16. Maximum daily dose: and duration:
17. Method of administration:
18. A categorical exclusion from preparing an environmental assessment (EA) as required under 21 CFR §511.1 (b)(10) is requested. ☐ Yes ☐ No
    If granted, the categorical exclusion and the INAD exemption do not relieve you of the responsibility for determining and meeting all Federal, state, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of the investigational drug. You should obtain a material safety data sheet (MSDS) for the investigational drug and follow the information in the MSDS to protect all individuals who may be exposed to the investigational drug.

II. For Animals Intended For Human Food Purposes

1. Date of CVM authorization letter:
2. Withdrawal period:
3. Acknowledgment that the date and place of slaughter will be reported to FDA and to Dr. William F. Leese, Director, USDA/FSIS, 300 7th Street, S.W., Room 514, Reporters Building, Washington, D.C. 20024, at least 10 days prior to shipment for slaughter. Experimentally treated animals will be identified to the inspector in charge of the slaughtering establishment when presented for antemortem inspection. ☐ Yes ☐ No
4. A waiver of requirements for notification of the date and place of slaughter after a 30-day holding and observation period following the required withdrawal period is requested.
   ☐ Yes ☐ No

III. Investigational New Animal Drug Labeling (Please select one)

1. New animal drugs for tests in vitro and in laboratory research animals:

☐ ***Caution.*** *Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.*

2. New animal drugs for clinical investigation in animals:

☐ ***Caution.*** *Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.*

3. New animal drugs for EXPORT in animals:

☐ ***Caution.*** *Contains a new animal drug for use only in investigational clinical trials. Not for use in humans. Edible products from animals used for investigation are not to be used for food in any manner contrary to the requirements of the country in which the clinical trials are to be conducted.*

If the drug is intended for food-producing animals, the label must also bear:

☐ *No official withdrawal time has been established for this product under the proposed investigational use.*

IV. Sponsor Information

1. Sponsor's name:
2. Sponsor's address:

3. Sponsor contact person's name:
4. Sponsor contact person's User ID:
5. Sponsor contact person's e-mail address:

NOTE: **IF THE INVESTIGATION IS DISCONTINUED, THE CENTER FOR VETERINARY MEDICINE SHOULD BE NOTIFIED, GIVING THE REASON AND DISPOSITION OF THE DRUG.**